

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Scott A. Guelcher, Ph.D.)

Pending before the court is the Motion to Exclude the Opinions and Testimony of Scott A. Guelcher, Ph.D. [ECF No. 1977] filed by Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert’s* core considerations for assessing expert

¹ Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 1977-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—and I will therefore reserve ruling until the expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Guelcher is a chemical engineer who has over twenty years of experience in his field. Ethicon challenges his testimony on several grounds.

a. Complications

Ethicon argues that Dr. Guelcher is unqualified to offer his complications opinions, and that the opinions are otherwise unreliable. Dr. Guelcher is not a medical doctor; instead, he is a chemical engineer. Dr. Guelcher has not examined patients, and he has not conducted differential diagnoses. Dr. Guelcher is simply not qualified to offer opinions on medical complications that may be caused by polymer degradation. Accordingly, Dr. Guelcher's opinions regarding complications resulting from alleged polypropylene degradation are **EXCLUDED**.

b. Mesh Properties

Ethicon asks the court to exclude Dr. Guelcher's degradation testimony, challenging it as unreliable on multiple fronts.

First, Ethicon argues that Dr. Guelcher's opinions should be excluded because he has chosen not to rely on his own testing regarding oxidative degradation. In response, the plaintiffs explain that Dr. Guelcher's study has not yet been published, has not been subject to peer review, and is otherwise unfinished. Interestingly, Ethicon argues that Dr. Guelcher should be required to testify regarding his study, while simultaneously pointing out that this court has already ruled testimony about the study is unreliable. *See, e.g., Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *25 (S.D. W. Va. Apr. 24, 2015). This argument is without merit. I will not exclude Dr. Guelcher's opinions merely because he chooses not to rely on his own incomplete studies. Ethicon's Motion on this issue is **DENIED**.

Second, Ethicon argues that Dr. Guelcher's degradation opinions should be

excluded because not all of the scientific literature upon which he relied examined Prolene specifically, but examined polypropylene generally. I disagree that the supposed distinction between Ethicon's Prolene and generic polypropylene renders studies on the latter unhelpful when discussing Prolene. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014) (rejecting Ethicon's argument as "wholly conceived by lawyers, unfounded in science"). Insofar as Ethicon seeks exclusion of Dr. Guelcher's opinions because he does not account for the differences between polypropylene and Prolene, its Motion is **DENIED**.

Third, Ethicon argues that Dr. Guelcher's opinions are unreliable because they are based in part on unpublished Ethicon studies—a Prolene suture study and a "seven-year dog study" of Prolene sutures—that allegedly do not support his opinion. Mem. 14 [ECF No. 1981]. Ethicon does not contest, however that its internal documents report evidence of polypropylene oxidation and degradation; instead, Ethicon challenges the conclusions of those reports by suggesting that degradation should be measured by methods different than those used in the studies. Such concerns are better suited for cross-examination. Moreover, I have previously ruled that an expert may testify as to a review of internal corporate documents for the purpose of explaining the basis of his expert opinions, as Dr. Guelcher does here. *Huskey*, 29 F. Supp. 3d at 702–03. I do not find that Dr. Guelcher's partial reliance on Ethicon's internal documents relating to degradation renders his opinions unreliable. Nor am I persuaded that evidence of these studies demonstrating the degradation of Prolene sutures will be prejudicial unless Ethicon can introduce

evidence that the sutures received FDA approval. Ethicon's Motion is **DENIED** on these points.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert

testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards

testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir.

2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert’s deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay.

The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

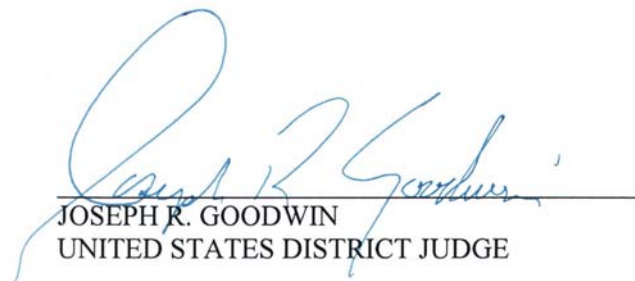
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part, GRANTS in part, and RESERVES in part** the Motion to Exclude the Opinions and Testimony of Scott A. Guelcher, Ph.D. [ECF No. 1977].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 31, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

AMENDED EXHIBIT A

Guelcher

<u>Case Name</u>	<u>Case Number</u>
Babcock, Marty	2:12cv01052
Barker, Daphne & Gary	2:12cv00899
Baughner, Dorothy	2:12cv01053
Beach, Harriet	2:12cv00476
Byrd, Myra & Richard	2:12cv00748
Collins, Fran Denise	2:12cv00931
Daino, Constance & Anthony	2:12cv01145
Dixon, Dennis W., re estate of Virginia M. Dixon, dec'd	2:12cv01081
Durham, Lois & Gerald	2:12cv00760
Forester, Karen & Joel	2:12cv00486
Freeman, Shirley & William	2:12cv00490
Freitas, Monica & Kenneth	2:12cv01146
Guinn, Susan	2:12cv01121
Hagans, Wendy	2:12cv00783
Harter, Beth & Stuart	2:12cv00737
Herrera-Nevarez, Rocio	2:12cv01294
Holmes, Jeanie	2:12cv01206
Holzerland, Mary & Darin	2:12cv00875
Hoy, Lois & Robert	2:12cv00876
Johnson, Myndal	2:12cv00498
Jones, Holly & Jason	2:12cv00443
Joplin, Deborah Lynn Debra Lynn	2:12cv00787
Kirkpatrick, Margaret	2:12cv00746
Kivel, Beverly	2:12cv00591
Lankston, Cheryl	2:12cv00755
Long, Heather	2:12cv01275
Massey, Donna & Charles	2:12cv00347-880
Morrison, Angela & Bradley	2:12cv00800
Quijano, Maria Eugenia	2:12cv00799
Rhynehart, Penny	2:12cv01119
Sacchetti, Denise	2:12cv01148
Schnering, Debra A. & Donald, Sr.	2:12cv01071
Scholl, Sheri & Gary	2:12cv00738
Shepherd, Donna	2:12cv00967
Smith, Cindy	2:12cv01149
Springer, Cherise & Marty	2:12cv00997
Stubblefield, Margaret	2:12cv00842
Thompson, Lisa & Roger	2:12cv01199
Thurston, Mary & Kenneth	2:12cv00505
Walker, Shirley & Roosevelt	2:12cv00873

Ex. A Gulecher

<u>Case Name</u>	<u>Case Number</u>
Warlick, Cathy	2:12cv00276
Waynick, Laura & David	2:12cv01151
Wheeler, Rebecca & David	2:12cv01088
Williams, Nancy	2:12cv00511
Wiltgen, Christine & Mark S.	2:12cv01216
Wright, Thelma	2:12cv01090